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8 Attorneys for Defendant
9 BAYER HEALTHCARE LLC

10 UNITED STATES DISTRICT COURT
11 NORTHERN DISTRICT OF CALIFORNIA
12 SAN FRANCISCO DIVISION

13 JOE V. SANCHEZ and SANDRA L.
14 ROARTY-SANCHEZ,,
15

16 Plaintiffs,

17 v.

18 BAYER HEALTHCARE
19 PHARMACEUTICALS, INC.; BAYER
20 HEALTHCARE LLC; GENERAL
21 ELECTRIC COMPANY; GE
22 HEALTHCARE, INC.; TYCO
23 INTERNATIONAL, INC.; COVIDIEN,
24 INC.; TYCO HEALTHCARE GROUP, LP;
25 MALLINCKRODT, INC.; and BRACCO
26 DIAGNOSTICS, INC.,
27

28 Defendants.

Case No. CV-08-0973 (EMC)

**ANSWER OF DEFENDANT BAYER
HEALTHCARE LLC**

**(Pending Transfer to: In re: Gadolinium
Contrast Dyes Products Liability
Litigation, MDL No. 1909, N.D. Ohio)**

[JURY TRIAL DEMANDED]

22 Defendant Bayer Healthcare LLC (hereinafter "BHC") responds to Plaintiffs'
23 Complaint as follows:

24 1. BHC denies that at any relevant time it manufactured, marketed or sold any
25 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
26 paragraph 1 to the extent that they relate to BHC. BHC is without knowledge or
27 information sufficient to form a belief as to the truth of the allegations in the first
28 sentence in paragraph 1 and the allegation that Plaintiff has impaired kidney function.

1 BHC admits, on information and belief, that the symptoms of nephrogenic systemic
2 fibrosis (“NSF”), formerly known as nephrogenic fibrosing dermopathy, may include
3 pain, that NSF may be fatal, and that currently, there is no known cure for NSF, although
4 various treatments have been employed with variable successes. The remaining
5 allegations in paragraph 1 are directed to other defendants and therefore no response is
6 required by BHC. To the extent that a response is required, BHC is without knowledge
7 or information sufficient to form a belief as to the truth of the remaining allegations in
8 paragraph 1.

9 2. The allegations in paragraph 2 state conclusions of law to which no
10 response is required by BHC. To the extent that a response is required, BHC is without
11 knowledge or information sufficient to form a belief as to the truth of the allegations in
12 paragraph 2, except that BHC denies that Plaintiffs are entitled to any relief from BHC.

13 3. BHC is without knowledge or information sufficient to form a belief as to
14 the truth of the allegations in paragraph 3, except that BHC denies that Plaintiffs are
15 entitled to any relief from BHC.

16 4. BHC is without knowledge or information sufficient to form a belief as to
17 the truth of the allegations in paragraph 4.

18 5. BHC denies that at any relevant time it manufactured, marketed or sold
19 Magnevist®, a gadolinium-based contrast agent. BHCP admits, on information and
20 belief, that Bayer HealthCare Pharmaceuticals Inc. (“BHCP”) markets and sells
21 Magnevist® in the United States. BHC denies, on information and belief, that BHCP
22 manufactures Magnevist®. BHC is without knowledge or information sufficient to form
23 a belief as to the truth of the remaining allegations in paragraph 5. For a further response,
24 to the extent that the Complaint contains allegations directed to BHCP by the use of the
25 terms “Bayer” or “Defendants” or otherwise, BHC responds on behalf of itself only and
26 makes no response on behalf of BHCP.

27 6. BHC admits that it is a limited liability company formed in Delaware and
28 that its principal place of business is located in New York. BHC denies any remaining

1 allegations in paragraph 6.

2 7. BHC admits that BHCP is a Delaware corporation with its principal place
3 of business in New Jersey. BHC denies the remaining allegations in paragraph 7.

4 8. BHC denies the allegations in paragraph 8 to the extent that they relate to
5 BHC. BHC admits, on information and belief, that at various times BHCP distributed,
6 sold, marketed and promoted Magnevist® in the United States. BHC denies, on
7 information and belief, that BHCP designed or manufactured Magnevist®. Because of
8 the vagueness and ambiguity of the remaining allegations in paragraph 8, BHC is without
9 knowledge or information sufficient to form a belief as to the truth of those allegations.

10 9. The allegations in paragraph 9 are directed to other defendants, and
11 therefore no response is required by BHC. To the extent that a response is required, BHC
12 is without knowledge or information sufficient to form a belief as to the truth of the
13 allegations in paragraph 9.

14 10. The allegations in paragraph 10 are directed to another defendant, and
15 therefore no response is required by BHC. To the extent that a response is required, BHC
16 admits, on information and belief, that General Electric Company is a corporation
17 incorporated under the laws of the State of New York with its principal place of business
18 in Connecticut. BHC is without knowledge or information sufficient to form a belief as
19 to the truth of the remaining allegations in paragraph 10.

20 11. The allegations in paragraph 11 are directed to another defendant, and
21 therefore no response is required by BHC. To the extent that a response is required, BHC
22 admits, on information and belief, that GE Healthcare Inc. is a corporation incorporated
23 under the laws of the State of Delaware with its principal place of business in New
24 Jersey. BHC is without knowledge or information sufficient to form a belief as to the
25 truth of the remaining allegations in paragraph 11.

26 12. The allegations in paragraph 12 are directed to other defendants, and
27 therefore no response is required by BHC. To the extent that a response is required, BHC
28 is without knowledge or information sufficient to form a belief as to the truth of the

1 allegations in paragraph 12.

2 13. The allegations in paragraph 13 are directed to other defendants, and
3 therefore no response is required by BHC. To the extent that a response is required, BHC
4 is without knowledge or information sufficient to form a belief as to the truth of the
5 allegations in paragraph 13.

6 14. The allegations in paragraph 14 are directed to another defendant, and
7 therefore no response is required by BHC. To the extent that a response is required, BHC
8 is without knowledge or information sufficient to form a belief as to the truth of the
9 allegations in paragraph 14.

10 15. The allegations in paragraph 15 are directed to other defendants, and
11 therefore no response is required by BHC. To the extent that a response is required, BHC
12 is without knowledge or information sufficient to form a belief as to the truth of the
13 allegations in paragraph 15.

14 16. The allegations in paragraph 16 are directed to other defendants, and
15 therefore no response is required by BHC. To the extent that a response is required, BHC
16 admits, on information and belief, that Mallinckrodt, Inc. is a corporation incorporated
17 under the laws of the State of Delaware with its principal place of business in Missouri.
18 BHC is without knowledge or information sufficient to form a belief as to the truth of the
19 remaining allegations in paragraph 16.

20 17. The allegations in paragraph 17 are directed to other defendants, and
21 therefore no response is required by BHC. To the extent that a response is required, BHC
22 is without knowledge or information sufficient to form a belief as to the truth of the
23 allegations in paragraph 17.

24 18. The allegations in paragraph 18 are directed to another defendant, and
25 therefore no response is required by BHC. To the extent that a response is required, BHC
26 is without knowledge or information sufficient to form a belief as to the truth of the
27 allegations in paragraph 18.

28 19. The allegations in paragraph 19 are directed to another defendant, and

1 therefore no response is required by BHC. To the extent that a response is required, BHC
2 admits, on information and belief, that Bracco Diagnostics, Inc. is a corporation
3 incorporated under the laws of the State of Delaware with its principal place of business
4 in New Jersey. BHC is without knowledge or information sufficient to form a belief as to
5 the truth of any remaining allegations in paragraph 19.

6 20. The allegations in paragraph 20 are directed to another defendant, and
7 therefore no response is required by BHC. To the extent that a response is required, BHC
8 is without knowledge or information sufficient to form a belief as to the truth of the
9 allegations in paragraph 20.

10 21. BHC admits that the Complaint refers to certain entities as “Defendants”.
11 BHC is without knowledge or information sufficient to form a belief as to the truth of any
12 remaining allegations in paragraph 21.

13 22. BHC is without knowledge or information sufficient to form a belief as to
14 the truth of the allegations in paragraph 22.

15 23. BHC admits, on information and belief, that NSF is characterized by
16 fibrosis of the skin and may involve fibrosis of other tissues throughout the body, that
17 symptoms of NSF may include discoloration, thickening, tightening and swelling of the
18 skin, that the symptoms of NSF may also include contractures around the joints that may
19 impair mobility, a burning or itching sensation, and pain, and that in some cases, the skin
20 may feel “woody”. BHC further admits, on information and belief, that there have been
21 reports of NSF involving the lungs, heart, liver and muscles, that the clinical course of
22 NSF can be progressive and may be fatal, and that currently, there is no known cure for
23 NSF, although various treatments have been employed with variable successes. BHC
24 denies, on information and belief, the remaining or inconsistent allegations in paragraph
25 23.

26 24. Because of the vagueness and ambiguity of the allegations in the first
27 sentence in paragraph 24, BHC is without knowledge or information sufficient to form a
28 belief as to the truth of those allegations. BHC denies, on information and belief, the

1 remaining allegations in paragraph 24.

2 25. BHC admits, on information and belief, that gadolinium is a heavy metal
3 and that it is not normally detected in the human body at the threshold levels of detection
4 typically employed. Because of the vagueness and ambiguity of the remaining
5 allegations in the first and second sentences in paragraph 25, BHC is without knowledge
6 or information sufficient to form a belief as to the truth of those allegations. BHC denies,
7 on information and belief, the remaining allegations in paragraph 25.

8 26. Because of the vagueness and ambiguity of the allegations in paragraph 26,
9 BHC is without knowledge or information sufficient to form a belief as to the truth of
10 those allegations.

11 27. BHC admits, on information and belief, that Magnevist® is cleared from
12 the body through the kidneys. Because of the vagueness and ambiguity of the allegations
13 in the second and third sentences in paragraph 27, BHC is without knowledge or
14 information sufficient to form a belief as to the truth of those allegations. BHC denies
15 that at any relevant time it manufactured, marketed or sold any gadolinium-based contrast
16 agents, and accordingly, BHC denies the remaining allegations in paragraph 27 to the
17 extent that they relate to BHC. The remaining allegations in paragraph 27 are directed to
18 other defendants and therefore no response is required by BHC. To the extent that a
19 response is required, BHC is without knowledge or information sufficient to form a belief
20 as to the truth of the remaining allegations in paragraph 27.

21 28. BHC denies the allegations in paragraph 28 to the extent that they relate to
22 BHC. The remaining allegations in paragraph 28 are directed to other defendants and
23 therefore no response is required by BHC. To the extent that a response is required, BHC
24 denies, on information and belief, that BHCP manufactured any gadolinium-based
25 contrast agents. BHC is without knowledge or information sufficient to form a belief as
26 to the truth of the remaining allegations in paragraph 28.

27 29. Because of the vagueness and ambiguity of the allegations in paragraph 29,
28 BHC is without knowledge or information sufficient to form a belief as to the truth of

1 those allegations.

2 30. BHC denies that at any relevant time it manufactured, marketed,
3 distributed, sold or administered any gadolinium-based contrast agents, and accordingly,
4 BHC denies the allegations in paragraph 30 to the extent that they relate to BHC. The
5 remaining allegations in paragraph 30 are directed to other defendants and therefore no
6 response is required by BHC. To the extent that a response is required, because of the
7 vagueness and ambiguity of the remaining allegations in paragraph 30, BHC is without
8 knowledge or information sufficient to form a belief as to the truth of those allegations.

9 31. BHC is without knowledge or information sufficient to form a belief as to
10 the truth of the allegations in paragraph 31.

11 32. BHC is without knowledge or information sufficient to form a belief as to
12 the truth of the allegations in paragraph 32.

13 33. BHC denies that at any relevant time it manufactured, marketed or sold any
14 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
15 paragraph 33 to the extent that they relate to BHC. The remaining allegations in
16 paragraph 33 are directed to other defendants and therefore no response is required by
17 BHC. To the extent that a response is required, BHC is without knowledge or
18 information sufficient to form a belief as to the truth of the remaining allegations in
19 paragraph 33.

20 34. BHC denies that at any relevant time it manufactured, marketed or sold any
21 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
22 paragraph 34 to the extent that they relate to BHC. The remaining allegations in
23 paragraph 34 are directed to other defendants and therefore no response is required by
24 BHC. To the extent that a response is required, BHC is without knowledge or
25 information sufficient to form a belief as to the truth of the remaining allegations in
26 paragraph 34.

27 35. BHC denies that at any relevant time it manufactured, marketed, distributed
28 or sold any gadolinium-based contrast agents, and accordingly, BHC denies the

1 allegations in paragraph 35 to the extent that they relate to BHC. The remaining
2 allegations in paragraph 35 are directed to other defendants and therefore no response is
3 required by BHC. To the extent that a response is required, BHC is without knowledge
4 or information sufficient to form a belief as to the truth of the remaining allegations in
5 paragraph 35.

6 36. BHC denies that at any relevant time it manufactured, marketed or sold any
7 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
8 paragraph 36 to the extent that they relate to BHC. The remaining allegations in
9 paragraph 36 are directed to other defendants and therefore no response is required by
10 BHC. To the extent that a response is required, BHC is without knowledge or
11 information sufficient to form a belief as to the truth of the remaining allegations in
12 paragraph 36.

13 37. The allegations in paragraph 37 purport to describe a September 2007 letter
14 to healthcare professionals, which is in writing and speaks for itself. To the extent that
15 Plaintiffs' allegations regarding the contents of that letter are inconsistent with the actual
16 language of the letter, BHC denies those allegations. BHC denies that at any relevant
17 time it manufactured, marketed or sold any gadolinium-based contrast agents, and
18 accordingly, BHC denies the remaining allegations in paragraph 37 to the extent that they
19 relate to BHC. The remaining allegations in paragraph 37 are directed to other
20 defendants and therefore no response is required by BHC. To the extent that a response
21 is required, BHC is without knowledge or information sufficient to form a belief as to the
22 truth of the remaining allegations in paragraph 37.

23 38. BHC denies that at any relevant time it manufactured, marketed or sold any
24 gadolinium-based contrast agents, and accordingly, BHC is without knowledge or
25 information sufficient to form a belief as to the truth of the allegations in paragraph 38.

26 39. BHC denies that at any relevant time it manufactured, marketed or sold any
27 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
28 paragraph 39 to the extent that they relate to BHC. The remaining allegations in

1 paragraph 39 are directed to other defendants and therefore no response is required by
2 BHC. To the extent that a response is required, BHC is without knowledge or
3 information sufficient to form a belief as to the truth of the remaining allegations in
4 paragraph 39.

5 40. BHC denies that at any relevant time it manufactured, marketed or sold any
6 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
7 paragraph 40 to the extent that they relate to BHC. The remaining allegations in
8 paragraph 40 are directed to other defendants and therefore no response is required by
9 BHC. To the extent that a response is required, BHC is without knowledge or
10 information sufficient to form a belief as to the truth of the remaining allegations in
11 paragraph 40.

12 41. BHC denies that at any relevant time it manufactured, marketed or sold any
13 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
14 paragraph 41 to the extent that they relate to BHC. The remaining allegations in
15 paragraph 41 are directed to other defendants and therefore no response is required by
16 BHC. To the extent that a response is required, BHC is without knowledge or
17 information sufficient to form a belief as to the truth of the remaining allegations in
18 paragraph 41.

19 42. The allegations in paragraph 42 state conclusions of law to which no
20 response is required by BHC. To the extent that a response is required, BHC denies that
21 at any relevant time it manufactured, marketed or sold any gadolinium-based contrast
22 agents, and accordingly, BHC denies the allegations in paragraph 42 to the extent that
23 they relate to BHC. The remaining allegations in paragraph 42 are directed to other
24 defendants and therefore no response is required by BHC. To the extent that a response
25 is required, BHC is without knowledge or information sufficient to form a belief as to the
26 truth of the remaining allegations in paragraph 42.

27 43. BHC denies that at any relevant time it manufactured, marketed or sold any
28 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in

1 paragraph 43 to the extent that they relate to BHC. The remaining allegations in
 2 paragraph 43 are directed to other defendants and therefore no response is required by
 3 BHC. To the extent that a response is required, BHC is without knowledge or
 4 information sufficient to form a belief as to the truth of the remaining allegations in
 5 paragraph 43.

6 **FIRST CAUSE OF ACTION**

7 44. BHC incorporates by reference its responses to the preceding paragraphs as
 8 if fully set forth herein.

9 45. BHC denies that at any relevant time it manufactured, marketed or sold any
 10 gadolinium-based contrast agents or any MRI or MRA machines, and accordingly, BHC
 11 denies the allegations in paragraph 45 to the extent that they relate to BHC. The
 12 remaining allegations in paragraph 45 are directed to other defendants and therefore no
 13 response is required by BHC. To the extent that a response is required, BHC is without
 14 knowledge or information sufficient to form a belief as to the truth of the remaining
 15 allegations in paragraph 45.

16 46. BHC denies that at any relevant time it manufactured, designed, sold,
 17 supplied or marketed any gadolinium-based contrast agents, and accordingly, BHC
 18 denies the allegations in paragraph 46 to the extent that they relate to BHC. The
 19 remaining allegations in paragraph 46 are directed to other defendants and therefore no
 20 response is required by BHC. To the extent that a response is required, BHC is without
 21 knowledge or information sufficient to form a belief as to the truth of the remaining
 22 allegations in paragraph 46.

23 **SECOND CAUSE OF ACTION**

24 47. BHC incorporates by reference its responses to the preceding paragraphs as
 25 if fully set forth herein.

26 48. BHC denies the allegations in paragraph 48 to the extent that they relate to
 27 BHC. BHC admits, on information and belief, that at various times BHCP distributed,
 28 sold and supplied Magnevist® in the United States. BHC denies, on information and

1 belief, that BHCP manufactured or designed Magnevist® and that BHC manufactured,
 2 designed, distributed, sold or supplied MRI or MRA machines. The remaining
 3 allegations in paragraph 48 are directed to other defendants and therefore no response is
 4 required by BHC. To the extent that a response is required, BHC is without knowledge
 5 or information sufficient to form a belief as to the truth of the remaining allegations in
 6 paragraph 48.

7 49. BHC denies that at any relevant time it manufactured or supplied any
 8 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
 9 paragraph 49 to the extent that they relate to BHC. The remaining allegations in
 10 paragraph 49 are directed to other defendants and therefore no response is required by
 11 BHC. To the extent that a response is required, BHC is without knowledge or
 12 information sufficient to form a belief as to the truth of the remaining allegations in
 13 paragraph 49.

14 50. BHC denies that at any relevant time it manufactured, marketed or sold any
 15 gadolinium-based contrast agents or any MRI or MRA machines, and accordingly, BHC
 16 is without knowledge or information sufficient to form a belief as to the truth of the
 17 allegations in paragraph 50.

18 51. BHC denies that at any relevant time it manufactured, designed, sold,
 19 supplied or marketed any gadolinium-based contrast agents, and accordingly, BHC
 20 denies the allegations in paragraph 51 to the extent that they relate to BHC. The
 21 remaining allegations in paragraph 51 are directed to other defendants and therefore no
 22 response is required by BHC. To the extent that a response is required, BHC is without
 23 knowledge or information sufficient to form a belief as to the truth of the remaining
 24 allegations in paragraph 51.

25 **THIRD CAUSE OF ACTION**

26 52. BHC incorporates by reference its responses to the preceding paragraphs as
 27 if fully set forth herein.

28 53. BHC denies that at any relevant time it manufactured, marketed, sold or

1 tested any gadolinium-based contrast agents, and accordingly, BHC denies the allegations
2 in paragraph 53 to the extent that they relate to BHC. The remaining allegations in
3 paragraph 53 are directed to other defendants and therefore no response is required by
4 BHC. To the extent that a response is required, BHC is without knowledge or
5 information sufficient to form a belief as to the truth of the remaining allegations in
6 paragraph 53.

7 54. BHC denies that at any relevant time it manufactured, marketed, sold or
8 tested any gadolinium-based contrast agents, and accordingly, BHC denies the allegations
9 in paragraph 54 to the extent that they relate to BHC. The remaining allegations in
10 paragraph 54 are directed to other defendants and therefore no response is required by
11 BHC. To the extent that a response is required, BHC is without knowledge or
12 information sufficient to form a belief as to the truth of the remaining allegations in
13 paragraph 54.

14 55. BHC denies that at any relevant time it tested, manufactured, designed,
15 sold, supplied or marketed any gadolinium-based contrast agents, and accordingly, BHC
16 denies the allegations in paragraph 55 to the extent that they relate to BHC. The
17 remaining allegations in paragraph 55 are directed to other defendants and therefore no
18 response is required by BHC. To the extent that a response is required, BHC is without
19 knowledge or information sufficient to form a belief as to the truth of the remaining
20 allegations in paragraph 55.

21 **FOURTH CAUSE OF ACTION**

22 56. BHC incorporates by reference its responses to the preceding paragraphs as
23 if fully set forth herein.

24 57. The allegations in paragraph 57 state conclusions of law to which no
25 response is required by BHC. To the extent that a response is required, BHC denies that
26 at any relevant time it designed, tested, manufactured, labeled, marketed, sold or
27 distributed any gadolinium-based contrast agents or any MRI or MRA machines, and
28 accordingly, BHC denies the allegations in paragraph 57 to the extent that they relate to

1 BHC. The remaining allegations in paragraph 57 are directed to other defendants and
2 therefore no response is required by BHC. To the extent that a response is required, BHC
3 is without knowledge or information sufficient to form a belief as to the truth of the
4 remaining allegations in paragraph 57.

5 58. BHC denies that at any relevant time it designed, manufactured, sold,
6 tested, marketed or distributed any gadolinium-based contrast agents or any MRI or
7 MRA machines, and accordingly, BHC denies the allegations in paragraph 58 to the
8 extent that they relate to BHC. The remaining allegations in paragraph 58 are directed to
9 other defendants and therefore no response is required by BHC. To the extent that a
10 response is required, BHC is without knowledge or information sufficient to form a belief
11 as to the truth of the remaining allegations in paragraph 58.

12 59. BHC denies that at any relevant time it manufactured, marketed, sold or
13 labeled any gadolinium-based contrast agents or any MRI or MRA machines, and
14 accordingly, BHC denies the allegations in paragraph 59 to the extent that they relate to
15 BHC. The remaining allegations in paragraph 59 are directed to other defendants and
16 therefore no response is required by BHC. To the extent that a response is required, BHC
17 is without knowledge or information sufficient to form a belief as to the truth of the
18 remaining allegations in paragraph 59.

19 60. The allegations in paragraph 60 state conclusions of law to which no
20 response is required by BHC. To the extent that a response is required, BHC denies that
21 at any relevant time it manufactured or marketed any gadolinium-based contrast agents or
22 any MRI or MRA machines, and accordingly, BHC denies the allegations in paragraph
23 60 to the extent that they relate to BHC. The remaining allegations in paragraph 60 are
24 directed to other defendants and therefore no response is required by BHC. To the extent
25 that a response is required, BHC is without knowledge or information sufficient to form a
26 belief as to the truth of the remaining allegations in paragraph 60.

27 61. BHC denies that at any relevant time it manufactured, marketed or sold any
28 gadolinium-based contrast agents or any MRI or MRA machines, and accordingly, BHC

1 denies the allegations in paragraph 61 to the extent that they relate to BHC. The
2 remaining allegations in paragraph 61 are directed to other defendants and therefore no
3 response is required by BHC. To the extent that a response is required, BHC is without
4 knowledge or information sufficient to form a belief as to the truth of the remaining
5 allegations in paragraph 61.

6 62. BHC denies that at any relevant time it manufactured, marketed or sold any
7 gadolinium-based contrast agents or any MRI or MRA machines, and accordingly, BHC
8 denies the allegations in paragraph 62 to the extent that they relate to BHC. The
9 remaining allegations in paragraph 62 are directed to other defendants and therefore no
10 response is required by BHC. To the extent that a response is required, BHC is without
11 knowledge or information sufficient to form a belief as to the truth of the remaining
12 allegations in paragraph 62.

13 63. BHC denies that at any relevant time it manufactured, marketed or sold any
14 gadolinium-based contrast agents or any MRI or MRA machines, and accordingly, BHC
15 denies the allegations in paragraph 63 to the extent that they relate to BHC. The
16 remaining allegations in paragraph 63 are directed to other defendants and therefore no
17 response is required by BHC. To the extent that a response is required, BHC is without
18 knowledge or information sufficient to form a belief as to the truth of the remaining
19 allegations in paragraph 63.

20 **FIFTH CAUSE OF ACTION**

21 64. BHC incorporates by reference its responses to the preceding paragraphs as
22 if fully set forth herein.

23 65. BHC denies that at any relevant time it manufactured, marketed or sold any
24 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
25 paragraph 65 to the extent that they relate to BHC. The remaining allegations in
26 paragraph 65 are directed to other defendants and therefore no response is required by
27 BHC. To the extent that a response is required, BHC is without knowledge or
28 information sufficient to form a belief as to the truth of the remaining allegations in

1 paragraph 65.

2 66. BHC denies that at any relevant time it manufactured, marketed or sold any
3 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
4 paragraph 66 to the extent that they relate to BHC. The remaining allegations in
5 paragraph 66 are directed to other defendants and therefore no response is required by
6 BHC. To the extent that a response is required, BHC is without knowledge or
7 information sufficient to form a belief as to the truth of the remaining allegations in
8 paragraph 66.

9 67. The allegations in paragraph 67 state conclusions of law to which no
10 response is required by BHC. To the extent that a response is required, BHC denies that
11 at any relevant time it manufactured, marketed or sold any gadolinium-based contrast
12 agents, and accordingly, BHC denies the allegations in paragraph 67 to the extent that
13 they relate to BHC. The remaining allegations in paragraph 67 are directed to other
14 defendants and therefore no response is required by BHC. To the extent that a response
15 is required, BHC is without knowledge or information sufficient to form a belief as to the
16 truth of the remaining allegations in paragraph 67.

17 68. BHC denies that at any relevant time it manufactured, marketed or sold any
18 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
19 paragraph 68 to the extent that they relate to BHC. The remaining allegations in
20 paragraph 68 are directed to other defendants and therefore no response is required by
21 BHC. To the extent that a response is required, BHC is without knowledge or
22 information sufficient to form a belief as to the truth of the remaining allegations in
23 paragraph 68.

24 69. BHC denies that at any relevant time it manufactured, marketed or sold any
25 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
26 paragraph 69 to the extent that they relate to BHC. The remaining allegations in
27 paragraph 69 are directed to other defendants and therefore no response is required by
28 BHC. To the extent that a response is required, BHC is without knowledge or

1 information sufficient to form a belief as to the truth of the remaining allegations in
2 paragraph 69.

3 **SIXTH CAUSE OF ACTION**

4 70. BHC incorporates by reference its responses to the preceding paragraphs as
5 if fully set forth herein.

6 71. BHC denies that at any relevant time it manufactured, marketed or sold any
7 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
8 paragraph 71 to the extent that they relate to BHC. The remaining allegations in
9 paragraph 71 are directed to other defendants and therefore no response is required by
10 BHC. To the extent that a response is required, BHC is without knowledge or
11 information sufficient to form a belief as to the truth of the remaining allegations in
12 paragraph 71.

13 72. BHC denies that at any relevant time it manufactured, marketed, sold,
14 labeled or promoted any gadolinium-based contrast agents, and accordingly, BHC denies
15 the allegations in paragraph 72 to the extent that they relate to BHC. The remaining
16 allegations in paragraph 72 are directed to other defendants and therefore no response is
17 required by BHC. To the extent that a response is required, BHC is without knowledge
18 or information sufficient to form a belief as to the truth of the remaining allegations in
19 paragraph 72.

20 73. BHC denies that at any relevant time it manufactured, marketed or sold any
21 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
22 paragraph 73 to the extent that they relate to BHC. The remaining allegations in
23 paragraph 73 are directed to other defendants and therefore no response is required by
24 BHC. To the extent that a response is required, BHC is without knowledge or
25 information sufficient to form a belief as to the truth of the remaining allegations in
26 paragraph 73.

27 74. BHC denies that at any relevant time it manufactured, marketed, sold,
28 labeled or promoted any gadolinium-based contrast agents, and accordingly, BHC denies

1 the allegations in paragraph 74 to the extent that they relate to BHC. The remaining
2 allegations in paragraph 74 are directed to other defendants and therefore no response is
3 required by BHC. To the extent that a response is required, BHC is without knowledge
4 or information sufficient to form a belief as to the truth of the remaining allegations in
5 paragraph 74.

6 75. BHC denies that at any relevant time it manufactured, marketed or sold any
7 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
8 paragraph 75 to the extent that they relate to BHC. The remaining allegations in
9 paragraph 75 are directed to other defendants and therefore no response is required by
10 BHC. To the extent that a response is required, BHC is without knowledge or
11 information sufficient to form a belief as to the truth of the remaining allegations in
12 paragraph 75.

13 76. The allegations in paragraph 76 state conclusions of law to which no
14 response is required by BHC. To the extent that a response is required, BHC denies that
15 at any relevant time it manufactured, marketed or sold any gadolinium-based contrast
16 agents, and accordingly, BHC denies the allegations in paragraph 76 to the extent that
17 they relate to BHC. The remaining allegations in paragraph 76 are directed to other
18 defendants and therefore no response is required by BHC. To the extent that a response
19 is required, BHC is without knowledge or information sufficient to form a belief as to the
20 truth of the remaining allegations in paragraph 76.

21 77. The allegations in paragraph 77 state conclusions of law to which no
22 response is required by BHC. To the extent that a response is required, BHC denies that
23 at any relevant time it manufactured, marketed, sold, labeled or promoted any
24 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
25 paragraph 77 to the extent that they relate to BHC. The remaining allegations in
26 paragraph 77 are directed to other defendants and therefore no response is required by
27 BHC. To the extent that a response is required, BHC is without knowledge or
28 information sufficient to form a belief as to the truth of the remaining allegations in

1 paragraph 77.

2 78. BHC denies that at any relevant time it manufactured, marketed or sold any
3 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
4 paragraph 78 to the extent that they relate to BHC. The remaining allegations in
5 paragraph 78 are directed to other defendants and therefore no response is required by
6 BHC. To the extent that a response is required, BHC is without knowledge or
7 information sufficient to form a belief as to the truth of the remaining allegations in
8 paragraph 78.

9 79. BHC denies that at any relevant time it manufactured, marketed or sold any
10 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
11 paragraph 79 to the extent that they relate to BHC. The remaining allegations in
12 paragraph 79 are directed to other defendants and therefore no response is required by
13 BHC. To the extent that a response is required, BHC is without knowledge or
14 information sufficient to form a belief as to the truth of the remaining allegations in
15 paragraph 79.

16 80. BHC denies that at any relevant time it manufactured, marketed or sold any
17 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
18 paragraph 80 to the extent that they relate to BHC. The remaining allegations in
19 paragraph 80 are directed to other defendants and therefore no response is required by
20 BHC. To the extent that a response is required, BHC is without knowledge or
21 information sufficient to form a belief as to the truth of the remaining allegations in
22 paragraph 80.

23 **SEVENTH CAUSE OF ACTION**

24 81. BHC incorporates by reference its responses to the preceding paragraphs as
25 if fully set forth herein.

26 82. BHC denies that at any relevant time it manufactured, marketed or sold any
27 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
28 paragraph 82 to the extent that they relate to BHC. The remaining allegations in

1 paragraph 82 are directed to other defendants and therefore no response is required by
2 BHC. To the extent that a response is required, BHC is without knowledge or
3 information sufficient to form a belief as to the truth of the remaining allegations in
4 paragraph 82.

5 83. BHC denies that at any relevant time it manufactured, marketed or sold any
6 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
7 paragraph 83 to the extent that they relate to BHC. The remaining allegations in
8 paragraph 83 are directed to other defendants and therefore no response is required by
9 BHC. To the extent that a response is required, BHC is without knowledge or
10 information sufficient to form a belief as to the truth of the remaining allegations in
11 paragraph 83.

12 84. BHC denies that at any relevant time it manufactured, marketed or sold any
13 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
14 paragraph 84 to the extent that they relate to BHC. The remaining allegations in
15 paragraph 84 are directed to other defendants and therefore no response is required by
16 BHC. To the extent that a response is required, BHC is without knowledge or
17 information sufficient to form a belief as to the truth of the remaining allegations in
18 paragraph 84.

19 **EIGHTH CAUSE OF ACTION**

20 85. BHC incorporates by reference its responses to the preceding paragraphs as
21 if fully set forth herein.

22 86. The allegations in paragraph 86 state conclusions of law to which no
23 response is required by BHC. To the extent that a response is required, BHC denies that
24 at any relevant time it manufactured, marketed or sold any gadolinium-based contrast
25 agents, and accordingly, BHC denies the allegations in paragraph 86 to the extent that
26 they relate to BHC. The remaining allegations in paragraph 86 are directed to other
27 defendants and therefore no response is required by BHC. To the extent that a response
28 is required, BHC is without knowledge or information sufficient to form a belief as to the

1 truth of the remaining allegations in paragraph 86.

2 87. BHC denies that at any relevant time it manufactured, marketed or sold any
3 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
4 paragraph 87 to the extent that they relate to BHC. The remaining allegations in
5 paragraph 87 are directed to other defendants and therefore no response is required by
6 BHC. To the extent that a response is required, BHC is without knowledge or
7 information sufficient to form a belief as to the truth of the remaining allegations in
8 paragraph 87.

9 88. BHC denies that at any relevant time it manufactured, marketed or sold any
10 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
11 paragraph 88 to the extent that they relate to BHC. The remaining allegations in
12 paragraph 88 are directed to other defendants and therefore no response is required by
13 BHC. To the extent that a response is required, BHC is without knowledge or
14 information sufficient to form a belief as to the truth of the remaining allegations in
15 paragraph 88.

16 **NINTH CAUSE OF ACTION**

17 89. BHC incorporates by reference its responses to the preceding paragraphs as
18 if fully set forth herein.

19 90. The allegations in paragraph 90 state conclusions of law to which no
20 response is required by BHC. To the extent that a response is required, BHC denies that
21 at any relevant time it designed, manufactured, marketed, sold or distributed any
22 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
23 paragraph 90 to the extent that they relate to BHC. The remaining allegations in
24 paragraph 90 are directed to other defendants and therefore no response is required by
25 BHC. To the extent that a response is required, BHC is without knowledge or
26 information sufficient to form a belief as to the truth of the remaining allegations in
27 paragraph 90.

28 91. BHC denies that at any relevant time it manufactured, marketed or sold any

1 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
2 paragraph 91 to the extent that they relate to BHC. The remaining allegations in
3 paragraph 91 are directed to other defendants and therefore no response is required by
4 BHC. To the extent that a response is required, BHC is without knowledge or
5 information sufficient to form a belief as to the truth of the remaining allegations in
6 paragraph 91.

7 92. BHC denies that at any relevant time it manufactured, marketed or sold any
8 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
9 paragraph 92 to the extent that they relate to BHC. The remaining allegations in
10 paragraph 92 are directed to other defendants and therefore no response is required by
11 BHC. To the extent that a response is required, BHC is without knowledge or
12 information sufficient to form a belief as to the truth of the remaining allegations in
13 paragraph 92.

14 93. BHC denies that at any relevant time it manufactured, marketed or sold any
15 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
16 paragraph 93 to the extent that they relate to BHC. The remaining allegations in
17 paragraph 93 are directed to other defendants and therefore no response is required by
18 BHC. To the extent that a response is required, BHC is without knowledge or
19 information sufficient to form a belief as to the truth of the remaining allegations in
20 paragraph 93.

21 **TENTH CAUSE OF ACTION**

22 94. BHC incorporates by reference its responses to the preceding paragraphs as
23 if fully set forth herein.

24 95. The allegations in paragraph 95 state conclusions of law to which no
25 response is required by BHC. To the extent that a response is required, BHC denies that
26 at any relevant time it manufactured, marketed or sold any gadolinium-based contrast
27 agents, and accordingly, BHC denies the allegations in paragraph 95, including
28 subparagraphs a. through g., to the extent that they relate to BHC. The remaining

1 allegations in paragraph 95 are directed to other defendants and therefore no response is
 2 required by BHC. To the extent that a response is required, BHC is without knowledge
 3 or information sufficient to form a belief as to the truth of the remaining allegations in
 4 paragraph 95.

5 96. BHC denies that at any relevant time it manufactured, marketed or sold any
 6 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
 7 paragraph 96 to the extent that they relate to BHC. The remaining allegations in
 8 paragraph 96 are directed to other defendants and therefore no response is required by
 9 BHC. To the extent that a response is required, BHC is without knowledge or
 10 information sufficient to form a belief as to the truth of the remaining allegations in
 11 paragraph 96.

12 **ELEVENTH CAUSE OF ACTION**

13 97. BHC incorporates by reference its responses to the preceding paragraphs as
 14 if fully set forth herein.

15 98. BHC is without knowledge or information sufficient to form a belief as to
 16 the truth of the allegations in paragraph 98.

17 99. BHC denies that at any relevant time it manufactured, marketed or sold any
 18 gadolinium-based contrast agents, and accordingly, BHC denies the allegations in
 19 paragraph 99 to the extent that they relate to BHC. The remaining allegations in
 20 paragraph 99 are directed to other defendants and therefore no response is required by
 21 BHC. To the extent that a response is required, BHC is without knowledge or
 22 information sufficient to form a belief as to the truth of the remaining allegations in
 23 paragraph 99.

24 100. BHC denies that Plaintiffs are entitled to any relief this action, including
 25 but not limited to the specific items of relief requested by Plaintiffs in the Complaint.

26 101. BHC denies each and every allegation in the Complaint that relates to or is
 27 directed to BHC unless such allegations are expressly admitted in this Answer.

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1 **DEFENSES**

2 Discovery and investigation may reveal that one or more of the following defenses
3 should be available to BHC in this matter. BHC accordingly preserves the right to assert
4 these separate and additional defenses. Upon completion of discovery, if the facts
5 warrant, BHC may withdraw any of these additional defenses as may be appropriate.
6 BHC further reserves the right to amend its Answer and defenses, and to assert additional
7 defenses and other claims, as discovery proceeds.

8 In setting forth the following separate and additional defenses, BHC does not
9 concede that it bears the burden of proof or persuasion as to any of them.

10 **FIRST DEFENSE**

11 Plaintiffs' Complaint, and each and every count contained therein, fails to state a
12 cause of action or claim upon which relief can be granted against BHC.

13 **SECOND DEFENSE**

14 Some or all of Plaintiffs' claims are barred, in whole or in part, by the applicable
15 statutes of limitations and/or statutes of repose.

16 **THIRD DEFENSE**

17 Plaintiffs' claims against BHC are barred, in whole or in part, by laches, waiver
18 and/or estoppel.

19 **FOURTH DEFENSE**

20 Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate
21 Plaintiffs' alleged damages.

22 **FIFTH DEFENSE**

23 The acts and omissions of Plaintiffs caused and/or contributed to the alleged
24 damages, thereby barring or reducing the amount of recovery under the doctrines of
25 contributory negligence and/or comparative negligence. Plaintiffs' recovery, if any,
26 therefore is barred or should be apportioned in accordance with applicable law.

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SIXTH DEFENSE

The alleged injuries sustained by Plaintiffs, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which BHC has no legal responsibility.

SEVENTH DEFENSE

If Plaintiffs suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs' assumption of the risk.

EIGHT DEFENSE

The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of BHC was not the proximate and/or competent producing cause of such alleged injuries and damages.

NINTH DEFENSE

The injuries and damages claimed by Plaintiffs, if any, are barred or must be reduced because those damages arose from the acts or omissions of persons or entities other than BHC.

TENTH DEFENSE

If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of the prescription drug Magnevist®. Plaintiffs' recovery is accordingly barred.

ELEVENTH DEFENSE

The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including BHC.

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TWELFTH DEFENSE

Magnevist® is a prescription pharmaceutical which was available only upon the prescription of a licensed physician and is indicated for use by physicians for only certain purposes. Accordingly, the claims in the Complaint are barred in whole or in part by the learned intermediary doctrine.

THIRTEENTH DEFENSE

Plaintiffs' recovery is barred to the extent that that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of Magnevist®, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art. Plaintiffs' recovery is further barred to the extent that Magnevist®, including its labeling approved by the FDA, complied with the state of scientific and medical knowledge available at the time of its design, testing, manufacture, distribution, marketing and sale.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred to the extent that Magnevist® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for its intended use. Plaintiffs' claims are barred to the extent that the warnings and instructions accompanying Magnevist® at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions.

FIFTEENTH DEFENSE

Plaintiffs' claims are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comment k.

SIXTEENTH DEFENSE

Plaintiffs' recovery is barred to the extent that the prescription drug Magnevist® complied with the applicable product safety regulations promulgated by the FDA, and compliance with such regulations demonstrates that due care was exercised with respect

1 to the design, manufacture, testing, marketing and sale of this prescription drug, and that
 2 it was neither defective nor unreasonably dangerous.

3 **SEVENTEENTH DEFENSE**

4 Any claims by Plaintiffs relating to alleged communications with regulatory
 5 agencies of the United States government are barred in whole or in part by operation of
 6 applicable law, including First and Fourteenth Amendment rights to petition the
 7 government.

8 **EIGHTEENTH DEFENSE**

9 Plaintiffs' claims are barred in whole or in part because the commercial speech
 10 relating to Magnevist® is protected under the First Amendment of the United States
 11 Constitution and the applicable state constitution.

12 **NINETEENTH DEFENSE**

13 Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by
 14 the doctrine of primary jurisdiction, in that the FDA is charged under law with
 15 determining the content of warnings and labeling for prescription drugs.

16 **TWENTIETH DEFENSE**

17 Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the
 18 Supremacy Clause of the United States Constitution by reason of the federal regulation of
 19 prescription drug manufacturing, testing, marketing, and labeling.

20 **TWENTY-FIRST DEFENSE**

21 Plaintiffs' claims are preempted, in whole or in part, by reason of the FDA's
 22 preamble to the *Requirements on Content and Format of Labeling for Human*
 23 *Prescription Drug and Biological Products*, 71 Fed. Reg. 3922 (Jan. 24, 2006).

24 **TWENTY-SECOND DEFENSE**

25 Plaintiffs cannot state a claim with regard to warnings and labeling for prescription
 26 drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the
 27 FDA.

TWENTY-THIRD DEFENSE

This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

TWENTY-FOURTH DEFENSE

Plaintiffs did not detrimentally rely on any labeling, warnings or information concerning Magnevist®.

TWENTY-FIFTH DEFENSE

Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

TWENTY-SIXTH DEFENSE

To the extent that Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

TWENTY-SEVENTH DEFENSE

To the extent that Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of BHC, if any, should be reduced accordingly.

TWENTY-EIGHT DEFENSE

Plaintiffs' Complaint fails to state a claim against BHC upon which relief can be granted as to costs, attorneys' fees, expenses, pre-judgment interest, post-judgment interest or estoppel.

TWENTY-NINTH DEFENSE

Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

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THIRTIETH DEFENSE

Plaintiffs' Complaint fails to state a claim against BHC upon which relief can be granted for several or joint and several liability.

THIRTY-FIRST DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

THIRTY-SECOND DEFENSE

BHC did not sell or distribute Magnevist® to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims for breach of warranty are barred by lack of privity between Plaintiffs and BHC.

THIRTY-THIRD DEFENSE

Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable state's Uniform Commercial Code or other applicable law.

THIRTY-FOURTH DEFENSE

Plaintiffs' Complaint fails to state a claim for fraud, statutory fraud, misrepresentation, omission, suppression and/or concealment, and fails to allege the circumstances constituting fraud with the particularity required by the Federal Rules of Civil Procedure.

THIRTY-FIFTH DEFENSE

Plaintiffs' Complaint fails to state a claim against BHC upon which relief can be granted for punitive or exemplary damages.

THIRTY-SIXTH DEFENSE

BHC denies any conduct for which punitive or exemplary damages could or should be awarded and denies that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages against BHC pursuant to the applicable standard(s) of proof.

THIRTY-SEVENTH DEFENSE

Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad and would violate BHC's constitutional rights as secured by the Fifth and Seventh Amendments to the United States Constitution, would violate its rights to due process and equal protection under the Fourteenth Amendment of the United States Constitution and the prohibition against excessive fines in the United States Constitution, and would contravene other provisions of the United States, California and Arizona Constitutions and any other applicable state Constitutions.

THIRTY-EIGHTH DEFENSE

Plaintiffs cannot recover punitive or exemplary damages against BHC because such an award, which is penal in nature, would violate BHC's constitutional rights under the United States Constitution and any other applicable state constitution, unless BHC is afforded the same procedural safeguards as are criminal defendants, including but not limited to the right to avoid self incrimination, the right to forego production and disclosure of incriminating documents and the right to the requirement of a level of proof beyond a reasonable doubt.

THIRTY-NINTH DEFENSE

Any imposition of punitive or exemplary damages in this case against BHC would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute, if imposed, an undue and unreasonable burden on interstate commerce.

FORTIETH DEFENSE

With respect to Plaintiffs' demand for punitive or exemplary damages, BHC specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under applicable state law.

FORTY-FIRST DEFENSE

Any award of punitive or exemplary damages against BHC is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North*

1 *America, Inc. v. Gore*, 517 U.S. 559, 134 L. Ed. 2d 809, 116 S. Ct. 1589 (1996), *State*
 2 *Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and *Philip*
 3 *Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

4 **FORTY-SECOND DEFENSE**

5 No act or omission of BHC was vile, base, willful, malicious, wanton, oppressive
 6 or fraudulent, or done with a conscious disregard for the health, safety, and rights of
 7 Plaintiffs and others, or for the primary purpose of increasing profits. Nor was any act or
 8 omission of BHC done with actual malice, fraud or oppression as defined in California
 9 Civil Code section 3294, or with actual malicious or gross negligence that evidences a
 10 willful, wanton, or reckless disregard for the safety of others, or an evil mind, and BHC
 11 did not commit actual fraud. Therefore, Plaintiffs' Complaint fails to state a claim upon
 12 which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint
 13 seeks damages in excess of those permitted by law. BHC asserts any statutory or judicial
 14 protection from punitive or exemplary damages that is available under the applicable law,
 15 and any award of punitive or exemplary damages is barred.

16 **FORTY-THIRD DEFENSE**

17 Plaintiffs' Complaint fails to state a claim for unlawful conduct under the Arizona
 18 consumer protection statute.

19 **FORTY-FOURTH DEFENSE**

20 Plaintiffs' claims are barred in whole or in part because the Arizona consumer
 21 protection statute is insufficiently definite to provide adequate or fair notice of the
 22 conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth
 23 Amendments to the United States Constitution and the due process protections of the
 24 applicable state constitution.

25 **FORTY-FIFTH DEFENSE**

26 Plaintiffs' claims are barred in whole or in part because Arizona consumer
 27 protection statute unconstitutionally burdens interstate business practices relating to
 28 prescription drugs, which are heavily regulated by the FDA.

FORTY-SIXTH DEFENSE

Venue is improper.

FORTY-SEVENTH DEFENSE

This Court is not the proper forum and is not a convenient forum for the just adjudication of Plaintiffs' claims.

FORTY-EIGHT DEFENSE

The injuries claimed by Plaintiffs, if any, were the result of an idiosyncratic reaction to the product.

FORTY-NINTH DEFENSE

Upon information and belief, Plaintiffs consented to the alleged wrongful conduct at issue, which bars Plaintiffs' claims in whole or in part.

FIFTIETH DEFENSE

To the extent that California law is applicable to Plaintiffs' claims, Plaintiffs' non-economic loss must be allocated in accordance with the provision of California Civil Code Section 1431.1 ("Proposition 51").

FIFTY-FIRST DEFENSE

To the extent that Arizona law is applicable to Plaintiffs' claims, Plaintiffs' Complaint fails to state a claim upon which relief can be granted for several or joint and several liability and any recovery should be apportioned pursuant to the Uniform Contribution Among Tortfeasors Act, A.R.S. § 12-2501, *et seq.*

FIFTY-SECOND DEFENSE

Any recovery by Plaintiffs is barred or should be reduced pursuant to A.R.S. § 12-2505 and/or common law and applicable statutes because of the contributory negligence, contributory fault, failure to mitigate damages and/or assumption of the risk by Plaintiffs.

FIFTY-THIRD DEFENSE

Pursuant to A.R.S. § 12-2506(B), BHC alleges that a person or entity not a party to this action was wholly or partially at fault in causing the alleged injuries and/or damages for which Plaintiffs seek recovery.

FIFTY-FOURTH DEFENSE

BHC denies making any express or implied warranties to Plaintiffs. In the alternative, BHC alleges that any and all warranties that may form a basis for Plaintiffs' claims were adequately disclaimed. In the alternative, Plaintiffs failed to give timely notice of the breach of warranty claims, as required by Arizona law and specifically, A.R.S. § 44-1521, *et seq.*, and Plaintiffs' claims are therefore barred.

FIFTY-FIFTH DEFENSE

Plaintiffs' claims are barred as a matter of law by A.R.S. § 12-683.

FIFTY-SIXTH DEFENSE

Plaintiffs' claims for punitive damages are barred by A.R.S. § 12-701(A).

FIFTY-SEVENTH DEFENSE

Under no circumstances may BHC be held derivatively liable for an award of punitive damages.

FIFTY-EIGHTH DEFENSE

BHC adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with BHC's defenses pleaded in this Answer.

WHEREFORE, BHC requests that Plaintiffs' Complaint be dismissed with prejudice, that judgment be entered in favor of BHC and against Plaintiffs, and that BHC be awarded the costs of this action, together with such other and further relief as may be appropriate.

JURY DEMAND

BHC hereby demands a trial by jury on all issues so triable.

Dated: March 11, 2008

DRINKER BIDDLE & REATH LLP

/s/ Rodney M. Hudson
 RODNEY M. HUDSON

Attorneys for Defendants
 BAYER HEALTHCARE LLC

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